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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,062

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EXAMINER

WAGGLE, JR, LARRY E

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

10/05/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,062	<b>Applicant(s)</b> GUILLAUME, FRANCIS	
	<b>Examiner</b> Larry E. Waggle, Jr	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-13 and 15-16 is/are rejected.
- 7) ☒ Claim(s) 5-11 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>16 May 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “40a” has been used to designate both a “bent portion,” disclosed on page 21, line 21 and a “bottom face,” disclosed on page 20, line 34. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because in Figure 1, it appears the reference character 20a should be 21a. There is no reference character 20a disclosed in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the

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replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 17, as disclosed on page 12, line 10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities:

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On page 20, line 34, the term "bottom face" should be referenced to as something other than 40a. The reference number 40a is reserved for a "bent portion."

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification discloses the blade (16) as a means for locking the two branches (13 and 14) apart (page, 14, lines 10-14). The specification is silent as to e.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-4 and 13-15, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

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Regarding claims 4 and 7, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-4, 13 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuke et al. (WO 01/85038 A1) in view of Axelson, Jr. et al. (US Patent 6,558,391).

Tuke et al. disclose resecting a top end of a tibia (113; Figure 14); and providing a set of instruments (Figure 1) including a first instrument (1, i.e. distractor used to verify ligamentary equilibrium in bending at 90° (Figure 20) and in extension (Figure 38)) comprising two branches (3 and 8) movable relative to each other and provided at their distal ends with means for pressing against the tibia and the femur (4 and 7), respectively and means for moving the distal ends of the branches mutually apart (i.e. interaction between the surgeon's hand and 3, 6, 8 and 20); and a second instrument (100) for cutting the femur fitted with means for positioning the instrument relative to the femur (i.e. flat surfaces interacting with 115 and 117 of the femur) and defining a plane distal cutting slot (103), wherein the means for pressing against the tibia defines a tibial bearing surface (113) that is substantially plane and the distracting instrument is further

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provided with a locator device (11 and 13) serving to locate the position for implanting at least one extramedullary pin (83; i.e. it is extramedullary in that a portion of the pin extends outside the bone) in a direction lying in a plane that is substantially parallel to the plane tibial bearing surface and that is situated at an adjustable distance (i.e. due to interaction between 52 and 53) from the tibial bearing surface, the locator device including an extra-femoral jig means (54) defining guide holes (15 and 16) (Figures 1-55 and pages 18-32).

Tuke et al. disclose the claimed invention except for the locator device serving to locate the position for implanting at least one pair of extramedullary pins through pin receiving cavities on either the medial or the lateral side of the femur, the extra-femoral jig means defining the direction along which the pins are implanted on either the medial or the lateral side of the femur, the means for positioning the second instrument relative to the femur being adapted to co-operate with projecting portions of the pins and the second instrument defining a plane posterior cutting slot. Axelson, Jr. et al. teach the use of a locator device (20) serving to locate the position for implanting two pairs of extramedullary pins (24) through pin receiving cavities on the medial and the lateral sides of the femur (Figure 6), extra-femoral jig means (22b and 22c) defining the direction along which the pins are implanted on either the medial or the lateral side of the femur, means for positioning (26 and slot in 42 and 44 interacting with 26) a second instrument (30) relative to the femur being adapted to co-operate with projecting portions of the pins (i.e. portions of the pins extending from the femur) and the second instrument defining plane posterior (Figure 9) and distal (Figure 12) cutting slots

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(Figures 4-12 and column 5, line 22 - column 8, line 14). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Tuke et al. with the locator device serving to locate the position for implanting two pairs of extramedullary pins through pin receiving cavities on the medial and the lateral sides of the femur, the extra-femoral jig means defining the direction along which the pins are implanted on either the medial or the lateral side of the femur, the means for positioning the second instrument relative to the femur being adapted to co-operate with projecting portions of the pins and the second instrument defining plane posterior and distal cutting slots in view of Axelson, Jr. et al. in order to provide a set of instruments for maintaining a more accurate alignment while multiple resection cuts are made in the femur.

**Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuke et al. (WO 01/85038 A1) in view of Axelson, Jr. et al. (US Patent 6,558,391) further in view of Gustilo et al. (US Patent 5,733,292).

Tuke et al. in view of Axelson, Jr. et al. disclose the claimed invention except for the means for pressing against the femur defining a convex elongate surface. Gustilo et al. teach a distraction instrument (Figure 1) comprising a means for pressing against the femur (100) defining a convex elongate surface (i.e. central-most section of 150) (Figures 1-5 and column 7, line 20 – column 10, line 13). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Tuke et al. in view of Axelson, Jr. et al. with the means for pressing against



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the femur defining a convex elongate surface in view of Gustilo in order to provide a more stable surface while distracting the knee joint.

Tuke et al. in view of Axelson, Jr. et al. further in view of Gustilo et al. disclose the claimed invention except for a transverse dimension of the convex elongate surface being less than about 9 mm. It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Tuke et al. in view of Axelson, Jr. et al. further in view of Gustilo et al. with the transverse dimension of the convex elongate surface being less than about 9 mm in order to permit a stable fit between the condyles of the femur, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

**Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuke et al. (WO 01/85038 A1) in view of Axelson, Jr. et al. (US Patent 6,558,391) further in view of Kempf et al. (DE 10335410 A1).

Tuke et al. in view of Axelson, Jr. et al. disclose the claimed invention except for the steps of locating the implantation positions in flexion and extension being performed with the kneecap of the patient generally in place. Kempf et al. teach evaluating the tension of knee elements with a set of instruments while the patella (i.e. kneecap) is in place (paragraphs 0004 and 0040). It would have been obvious to a person having ordinary skill in that art at the time of the invention to construct the invention of Tuke et al. in view of Axelson, Jr. et al. with evaluating the tension of knee elements with a set

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of instruments while the kneecap is in place in view of Kempf et al. in order to mimic the natural physiological conditions of the knee joint while verifying ligamentary equilibrium.

***Allowable Subject Matter***

Claims 5-6 and 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7 and 14 are objected to as each being dependent upon a rejected base claim, but would be allowable if rewritten in independent form and to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

**Smith et al. (EP 1348382 A2) disclose a set of instruments for implanting a knee prosthesis.**

**Wehrli (US Patent 4,938,762) disclose a set of instruments for implanting a knee prosthesis.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry E. Waggle, Jr whose telephone number is (571)270-7110. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. E. W./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775